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In The

Supreme Court of the United States

October Term, 1984

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

vs.

CIBA-GEIGY CORPORATION,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF FOR THE GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION AS *AMICUS CURIAE*

IN SUPPORT OF REVERSAL

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TABLE OF CONTENTS

Page

Preliminary Statement 1

Interest of *Amicus Curiae* 1

Summary of Argument 3

Argument:

I. The Third Circuit applied an erroneous legal standard in holding that appearance features had secondary meaning and were not functional. 5

II. The lower court's attempt to mandate product appearance differences for the purpose of "informed consent" is unsupported as a matter of law or policy. 11

III. The courts below disregarded the *Ives* decision and improperly applied Section 43(a) of the Lanham Act. 16

Conclusion 20

TABLE OF CITATIONS

Cases Cited:

Aloe Creme Laboratories, Inc. v. Milsan, Inc., 423 F.2d 845 (5th Cir. 1970) 8

Application of Deister Concentrator Co., 289 F.2d 496 (C.C.P.A. 1961) 8

Contents

Page

Application of Honeywell, Inc., 532 F.2d 180 (C.C.P.A. 1976) 9

Bayer Co. Inc. v. United Drug Co., 272 F. 505 (S.D.N.Y. 1921) 9

Carter-Wallace, Inc. v. Procter Gamble Co., 434 F.2d 794 (9th Cir. 1970) 8

Coca-Cola v. Koke Co., 254 U.S. 143, 65 L. Ed. 189 (1920) 6

Coca Cola v. Snow Crest Beverages, Inc., 64 F. Supp. 980 (D. Mass. 1946), aff'd 162 F.2d 280 (1st Cir.), cert. denied 322 U.S. 809 (1947) 6, 17

Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234, 11 L. Ed. 2d 669, 84 S. Ct. 779 (1964) 3, 18

Eli Lilly & Co. v. Wm. R. Warner & Co., 275 F. 752 (3rd Cir. 1921) 18

Information Clearing House v. Find Magazine, 492 F. Supp. 147 (S.D.N.Y. 1980) 7

Inwood Laboratories, Inc. v. Ives Laboratories, Inc., 456 U.S. 844, 72 L. Ed. 2d 606, 102 S. Ct. 2182 (1982) 2, 3, 4, 5, 7, 16, 18

Ives Laboratories v. Darby Drug Co., Inc., 488 F. Supp. 394 (E.D.N.Y.) 10

Kellogg Co. v. National Biscuit Co., 305 U.S. 111, 83 L. Ed. 73 (1938) 3

Contents

Page

Marion Laboratories, Inc. v. Michigan Pharmacal Corp., 388 F. Supp. 762 (E.D. Mich. 1972) 6

Mushroom Makers, Inc. v. R.G. Barry Corp., 441 F. Supp. 1220 (S.D.N.Y. 1977) aff'd, 580 F. 2d 44 (2d Cir. 1978) cert. denied, 439 U.S. 116 (1979) 7

Norwich Pharmacal v. Sterling Drug, Inc., 271 F. 2d 569 (2d Cir. 1959), cert. denied, 362 U.S. 919 (1960) 6, 8

Pennwalt Corp. v. Zenith Laboratories, Inc., 472 F. Supp. 413 (E.D. Mich. 1979)..... 19

Pharmaceutical Society of NY Inc. v. Lefkowitz, 454 F. Supp. 1175 (S.D.N.Y. 1978), aff'd 586 F.2d 953 (2d Cir. 1978) 14

Ro[illegible] Whitney Corp., et al. v. Smith, Klein & French Laboratories, 207 F.2d 190 (9th Cir. 1953) 6

Sears Roebuck & Co. v. Stiffel Co., 376 U.S. 11 L. Ed. 2d 661, 84 S. Ct. 784 (1964) 3, 18

Singer Mfg. Co. v. June Mfg. Co., 163 U.S. 169 (1896) . 3

SK&F v. Premo, 625 F.2d 1062 .....17, 18

Smith, Klein & French Laboratories v. Brouder, 125 U.S.P.Q. 299 (S.D. Tex. 1959) 6

Smith, Klein & French Laboratories v. Clark & Clark, 157 F.2d 725 (3rd Cir. 1946)..... 6

Contents

Page

Upjohn Co. v. Schwartz, 246 F.2d 254 (2d Cir. 1957) ... 6

Virginia State Board of Pharmacy v. Virginia Citizens' Consumer Council, Inc., 425 U.S. 748, 48 L. Ed. 2d 346, 96 S. Ct. 1817 (1976) 4, 5, 13, 16

Warner & Co. v. Eli Lilly & Co., 265 U.S. 526 (1924) 3, 6, 18, 19

Statutes Cited:

Lanham Act:

Section 32 .....5, 16, 18

Section 43(a) 5, 16, 18

21 U.S.C. § 321, et seq. 13

Other Authorities Cited:

Annual Prescription Survey by the Albany College of Pharmacy, Medical Marketing and Media, April 1978 14

Consumer Reports, January 1975 13

FDA Consumer Magazine, March 1973 13

FDA Consumer Magazine, February 1978 13

McCarthy, Trademarks and Unfair Competition, Section 12:1 at 405-6 7

Contents

Page

Multi-Sources Drugs: An Acceleration in the Use of Lower-Costing Substitutes?, Reynolds Securities Information Report, May 13, 1977 14

N.Y. Education Law, Section 6810 (McKinney's Supp. 1981) 15

N.Y. Education Law, Section 6816 (McKinney's Supp. 1981) 16

The Pill Book, Bantam Books (1982) 8

Restatement of Torts, §§ 711, 713 18

Staff Report to Federal Trade Commission Drug Product Selection 96 (1979) 12, 13

Warner, Consumer Protection and Prescription Drugs: The Generic Substitution Laws, 67 Ky. L. J. 389 (1979) 15

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PRELIMINARY STATEMENT

This Amicus Brief is presented by the Generic Pharmaceutical Industry Association pursuant to Rule 36.1 of the Supreme Court Rules with the written consent of both parties on file with the Clerk of this Court. This brief supports the petition of Bolar Pharmaceutical Co., Inc. that a writ of certiorari issue to review the decision of the Court of Appeals for the Third Circuit.

INTEREST OF AMICUS CURIAE

The Generic Pharmaceutical Industry Association was formed in 1980 by a group of independent generic drug manufacturers,

distributors and retailers to seek solutions to common problems having an economic impact on the distribution and sale of generic drugs. Many of these problems relate to the implementation of the laws enacted in all 50 States, the District of Columbia and Puerto Rico, which are intended to encourage the substitution of lower cost, therapeutically equivalent, generic drugs for unpatented high priced, heavily promoted brand name drugs as a means of reducing health care costs. The Association's member companies account for a substantial portion of the sales of independently manufactured generic prescription drugs.

The questions raised in this case transcend the specific petitioner and facts and have a direct economic impact on the generic pharmaceutical industry, government medical reimbursement programs and consumers of prescription drugs. Prior to the decision below and similar recent decisions in the Third Circuit, a long line of precedents had held that the size, color and shape of prescription drugs were functional because those appearance features helped patients to identify the medication and, therefore, could not be the exclusive property of a single manufacturer. Dozens of identically colored drugs made by different manufacturers had, in fact, coexisted in the marketplace for many years without engendering any legal controversy. This Court's decision in the *Ives*[1] case, although not directly addressing all of the relevant legal issues, was generally supportive of the sale of generic equivalent drugs which look like the brand name drug which the patient was accustomed to taking. The Second Circuit's ultimate decision on remand in the *Ives* case affirmed a district court decision permitting the sale of a generic drug which was identical to a brand name drug in appearance. The facts in that case are indistinguishable from this case and the dissent below mirrors the opinion of the district court in the *Ives* case.

The conflict between the decisions in the Second and Third Circuits has created a new game in which generic drug companies are forced to seek declaratory judgment relief in the Second Circuit before they are sued in the Third Circuit. The victims of this game are the members of Amicus who are unable to make rational

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1. *Inwood Laboratories v. Ives Laboratories, Inc*. 456 U.S. 844 (1982).

business judgments due to the uncertainty as to which Court will ultimately decide a particular case. Unless this Court settles these issues by establishing a uniform legal standard, the Third Circuit's decisions will force the generic drug industry to abandon the practice of manufacturing generically equivalent drugs in the identifying colors with which the patient is familiar. The real losers will be the sick and the aged who will be deprived of the primary means by which they identify their medications. The economic, health and safety implications of that deprivation are staggering, and it should not be permitted to occur without a full hearing in this Court.

SUMMARY OF ARGUMENT

The basic question raised by all of the drug appearance cases is: What does the capsule or tablet appearance actually mean to patients? If patients associate the appearance of a product with a particular manufacturer of the medication, then it serves the same function as a trademark and should be protected. But, if patients rely on tablet appearance to identify the medication itself, rather than a particular manufacturer, all FDA approved, equivalent medications should be entitled to have the same appearance. That conclusion is consistent with a series of decisions by this Court spanning almost one hundred years.[2]

The District Court opinion below contains an unequivocal finding that patients rely on the appearance of prescription drugs to identify the medication and not to identify a source of origin. Judge Sarokin found that, when a patient who has previously been taking a brand name product receives a different looking generic equivalent,

> " . . .the patient will usually call his physician or pharmacist to inquire whether the correct medication has been dispensed."

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2. *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169 (1896); *Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924); *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 83 L.Ed. 73 (1938); *Sears Roebuck & Co. v. Stiffel Co.*, 376 U.S. 11 L. Ed. 2d 661, 84 S. Ct. 784 (1964); *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 11 L. Ed. 2d 669, 84 S. Ct. 779 (1964); and *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 72 L.Ed. 2d 606, 102 S.Ct. 2182 (1982).

That finding establishes that drug appearance features identify the medicine, and not its source. It should have resulted in an immediate dismissal of all of Ciba's claims. Instead, Judge Sarokin found that the "fears and anxieties" of patients, arising from the belief that the wrong medication had been dispensed, would be quelled once the pharmacist provided an explanation and that such an explanation was necessary so that the patient could exercise "informed consent" to generic substitution. The concept of "informed consent" has no identifiable counterpart in the state or federal laws of unfair competition and is an unwarranted attempt at judicial legislation to supplement the State substitution laws.[3]

In *Ives,* this Court rejected the notion that a "watering down" of the standards for determining contributory infringement was an appropriate solution to any problem relating to illegal substitution. The watering down of the standards for determining secondary meaning is equally repugnant. It makes no sense to find that the appearance of a drug product has acquired secondary meaning based on inferences drawn from advertising which never reaches the patient and presumptions from the fact that the product appearance was copied, when the direct evidence of the patient's state of mind establishes that the appearance features identify the medicine and not the manufacturer. Yet, that is precisely what the lower courts did in this case.

Ironically, the state substitution laws were enacted because the manner in which prescription pharmaceuticals were previously dispensed left the consumer with no choice whatsoever in the selection of the source of its drug products. Those laws reflect a belief by the states that the persistent use of the brand name as though it was the generic name for a drug during the period of patent exclusivity directly contributes to inordinately high drug prices after expiration of the patent monopoly. The substitution laws represent state action in aid of the welfare of its citizens

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3. This Court has made it clear that states are in a position to ensure that pharmacists meet high standards of integrity or lose their licenses to practice. *Virginia State Board of Pharmacy v. Virginia Citizens' Consumer Council, Inc.,* 425 U.S. 748, 48 L. Ed. 2d 346, 96 S. Ct. 1817 (1976). There is no need for the courts to rewrite existing statutes, and no authority for them to do so.

which should have been given full respect by the Third Circuit, absent any conflicting and overriding federal law which mandated a contrary result. This Court has previously recognized the need to avoid judicial decisions which force the poor and the aged to choose between the alleviation of pain and the enjoyment of basic necessities.[4] It should not force consumers to live with even a moment of fear and anxiety about their medications as the price for buying a lower cost generic drug.

It is also evident that the Third Circuit watered down, if not outright ignored, this Court's rejection of "reasonable anticipation" as a proper test for determining whether a generic drug manufacturer is liable for illegal substitution at the retail level. The doctrine of contributory infringement restated by this Court in *Ives* stems from basic principles of unfair competition law which existed for many years under the common law and remain constant, irrespective of whether the issue is presented under Section 32 or Section 43(a) of the Lanham Act. Those principles preempt any contrary interpretation of state law.

ARGUMENT

I.

The Third Circuit applied an erroneous legal standard in holding that appearance features had secondary meaning and were not functional.

The courts below correctly stated that to succeed on a claim of unprivileged imitation either under the common law, or under Section 43(a) of the Lanham Act, it must be established that the appearance features for which injunctive relief is sought have (1) acquired secondary meaning and (2) are not functional. These prerequisites have been established by a century of consistent holdings by this Court[5] which recognize that imitation is the lifeblood of competition and that unhindered duplication of products must be permitted subject only to such limitations as are necessary to prevent consumer confusion with respect to the

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4. *Virginia State Board of Pharmacy, supra.*

5. *See* Footnote 2.

source of origin of products. Accordingly, the pink color of Pepto-Bismol[6] and the brown color of Coca-Cola[7] were not protected against copying since these features were associated in the mind of the public with the product itself and do not serve to identify any particular producer. Indeed, until the recent group of decisions barring generic drug manufacturers from selling identically colored pharmaceutical capsules, the cases dealing with drug products uniformly rejected attempts to enjoin a competitor from the use of the same color, even in instances where there was evidence to establish acts amounting to wrongful substitution or passing off at the consumer level. *Warner & Co. v. Lilly & Co., supra; Norwich Pharmacal v. Sterling Drug, Inc.*, 271 F.2d 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960); *Upjohn Co. v. Schwartz*, 246 F.2d 254 (2d Cir. 1957); *Smith, Klein & French Laboratories v. Clark & Clark*, 157 F.2d 725 (3rd Cir. 1946); *Marion Laboratories, Inc. v. Michigan Pharmacal Corp.*, 388 F.Supp. 762 (E.D. Mich. 1972).[8]

It is self-evident from the foregoing decisions that the burden is on the party asserting rights in the appearance of a product to establish the consumer's state of mind, *i.e.*, to establish that a product appearance feature has secondary meaning because it signifies a source of origin to the consumer. Recent cases recognize that the only truly meaningful way of satisfying the burden of proving consumer attitudes is to undertake a survey of consumer

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6. *Norwich Pharmacal Co. v. Sterling Drug, Inc.*, 271 F. 2d 569 (2d Cir. 1959).

7. *Coca-Cola v. Koke Co.*, 254 U.S. 143, 65 L. Ed. 189 (1920); *Coca Cola v. Snow Crest Beverages, Inc.*, 64 F. Supp. 980 (D. Mass. 1946), *aff'd* 162 F. 2d 280 (lst Cir.), *cert. denied* 322 U.S. 809 (1947).

8. The only pharmaceutical product cases found in which the appearance of the product was actually enjoined are the Dexadrine cases, *Ross-Whitney Corp., et al. v. Smith, Klein & French Laboratories*, 207 F. 2d 190 (9th Cir. 1953); *Smith, Klein & French Laboratories v. Brouder*, 125 U.S.P.Q. 299 (S.D. Tex. 1959). However, both of those cases involved a unique pill shape in addition to color.

reaction to the products under actual market conditions.[9] No such surveys were conducted in this case. Instead, the trial court improperly shifted the burden of proving the absence of secondary meaning to the generic manufacturer based on the clearly erroneous legal presumption that the act of copying the product appearance constitutes proof of secondary meaning. That presumption is the ultimate Catch-22 since a party who copies a product appearance in the belief that consumers associate that appearance with the product itself, and not with any particular manufacturer, will, by the mere act of copying, create a contrary presumption. This Court in *Ives* recognized that the functionality of capsule colors could provide at least one legitimate reason for producing an imitative product. In any event, this case does not involve the copying of arbitrary packaging features in a situation where consumers may be unfairly confused by adjacently displayed products at the point of purchase. In that environment, where the consumer must select a product, there may be some justification for a presumption based on simulation of appearance. In this case, the patient does not even see the product before it is purchased, and its appearance plays no role in product selection.

There is, of course, no legitimate or compelling reason to assume that the color of a prescription drug product is likely to designate a source of origin. To the contrary, if appearance was truly intended to designate the origin of a drug product, it would obviously make more sense for each company to use the same color for all of its products rather than to use a different color for each medication and even for each dosage of the same medication. Nor would there be any reason to include a Product Identification Section in the industry sponsored Physicians' Desk

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9. Some recent decisions have drawn negative inferences from the failure of a party to conduct such surveys where it had the financial means to do so. *Mushroom Makers, Inc. v. R. G. Barry Corp.*, 441 F. Supp. 1220, 1231 (S.D.N.Y. 1977) *aff'd*, 580 F. 2d 44 (2d Cir. 1978) *cert. denied*, 439 U.S. 116 (1979); *Information Clearing House v. Find Magazine*, 492 F. Supp. 147, 160 (S.D.N.Y. 1980); McCarthy, *Trademarks and Unfair Competition*, Section 12:1 (pp. 405-6).

Reference which includes color photographs to help doctors identify each drug.[10] These telltale signs of the functionality of drug colors cannot be swept away on the irrelevant ground that the initial color selection was arbitrary and any color could have been used, although that is precisely the position taken in the recent decisions of the Third Circuit. It seems highly unlikely that the same logic would be applied to a traffic light or a fire engine although the initial selection of their colors was also a matter of arbitrary choice.

The decisions below also erroneously rely on evidence of extensive sales and advertising to support the claim that capsule appearance has secondary meaning to consumers. The underlying rationale for considering such circumstantial evidence is an inference that widespread advertising and exposure of a product feature to a substantial number of people in the relevant buyer class will eventually create in the buyer's mind an association between that feature and a single source. While a seller's efforts to expose buyers to product appearance may be relevant evidence from which secondary meaning may be inferred in some cases, such efforts do not automatically lead to an irrebuttable presumption that advertising or sales have been effective in creating secondary meaning. The test of secondary meaning is the effectiveness, not the extensiveness, of the effort to create it. *Aloe Creme Laboratories, Inc. v. Milsan, Inc.*, 423 F.2d 845 (5th Cir. 1970); *Carter-Wallace, Inc. v. Procter & Gamble Co.*, 434 F.2d 794 (9th Cir. 1970). The mere fact that a particular product is popular and enjoys a dominant market position also does not establish that the public associates the product appearance with a particular source. *Norwich Pharmacal v. Sterling Drug, Inc.; supra; Application of Deister Concentrator Co.*, 289 F.2d 496

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10. In the introduction to *The Pill Book*, Bantam Books (1982), Dr. Frank Field, the well-known television science commentator states: "Think of the value of accurate, life-sized color pictures of pills if, for example, you are in an emergency situation with an elderly relative where various pills are mixed together in an unmarked pillbox." There are over one million copies of *The Pill Book* in print and this statement concerning the functionality of color cannot be lightly disregarded.

(C.C.P.A. 1961); *Application of Honeywell, Inc.*, 532 F.2d 180 (C.C.P.A. 1976).

The unique circumstances under which prescription drugs are marketed actually eliminates any basis for an inference that patients will associate the appearance of a capsule with a single source of origin rather than with the medication itself. All of the massive advertising and promotion by the brand name manufacturers is directed at physicians and pharmacists, and no advertising of any kind is ever directed at consumers. Thus, the only information in the patient's possession is the information on the prescription vial and on the pill itself. That information does not inform the patient that the color or shape of the pill is a trademark and that all pills with that name and appearance are made by a single producer. Indeed, patients taking a drug are often switched from one dose to another and are exposed to a different color each time there is a change in their medication.[11] The logical inference, if inferences are to be drawn at all, is that color was intended to convey information about the medicine. As stated in *Bayer Co., Inc. v. United Drug Co.*, 272 F. 505 (S.D.N.Y. 1921)

> "The plaintiff argues that . . .it is impossible to get a trade-mark for an 'ethical' remedy, which apparently means a remedy not directly advertised or sold to the public. But it must not blow hot and cold. If a manufacturer thinks it undesirable to advertise and sell drugs direct, the inevitable con sequence of adhering to that standard is that no trade-mark among consumers can be acquired, because they can know nothing of it." 272 F. at 512.

With these words, Judge Learned Hand held that the word "Aspirin" identified a medication and not a source of origin. Clearly, he would have had a much easier time in reaching the

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11. The Ciba drug involved in this action is sold in three different dosage strengths and each dosage has its own color.

same conclusion with respect to appearance features which, by their very nature, would be less likely to have trademark significance to consumers than the name of the product.[12]

The undisputed findings of the District Court below (which were never even mentioned by the Third Circuit in its opinion) dramatically serve to demonstrate the legal impropriety of substituting presumptions and inferences concerning secondary meaning for direct proof of the consumer's state of mind. Judge Sarokin held that when a patient already on a brand name drug receives a prescription containing a different looking generic equivalent drug " . . .the patient will usually call his physician or pharmacist to inquire whether the correct medication has been dispensed." (App. 22). Indeed, the District Court also acknowledged that the uncertainty created by the differences in appearance would cause the typical patient to suffer some anxiety. Judge Sarokin failed to give that uncontradicted finding any weight with respect to the secondary meaning and functionality issues. Instead, he relied on expert testimony which established that the patient's initial anxiety would be quelled after the physician or pharmacist explained to the patient that different colors signify different manufacturers rather than different medicines. In finding that an explanation to the patient was essential to clear up the patient's belief that the wrong medicine had been dispensed, Judge Sarokin stated (App. 22):

> "If the fears and anxieties of the patient could not be quelled by such an explanation, it may well be that a finding of functionality would be mandated."

It apparently never occurred to Judge Sarokin that if patients actually believed that the appearance of a drug product identified its source, they would not need the explanation! The need for

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12. Both the dissent below and Judge Nickerson's Opinion in *Ives Laboratories v. Darby Drug Co., Inc.*, 488 F. Supp. 394 (E.D.N.Y) expressly rejected the notion that extensive advertising to physicians and pharmacists would or could have any bearing on whether product appearance features had secondary meaning to consumers.

an explanation is the ultimate proof that tablet appearance is functional because it aids the patient in confirming that the correct medication is dispensed. It is also the ultimate proof that drug colors do not have secondary meaning.[13]

Judge Sarokin's opinion is silent with regard to such questions as the circumstances under which the patient will first discover that a different colored medication was dispensed; the length of time which will elapse until the patient can receive the essential explanation; the dangers caused by the patient's failure to take essential medication during the intervening period; and the cost to physicians and pharmacists in taking the time necessary for such explanations. It is naive to believe that patients actually open prescription vials in the drug store to check the color of the pills. Clearly, the foregoing factors will combine to provide Ciba and other brand name manufacturers with a competitive advantage over a generic drug having a different appearance. This Court has repeatedly held that the purpose of the laws relating to unfair competition is to prevent confusion among consumers and to promote competition between manufacturers. In contrast, the Third Circuit's decision in this case creates confusion and anxiety for patients and an unfair competitive advantage for brand name manufacturers.

II.

The lower court's attempt to mandate product appearance differences for the purpose of "informed consent" is unsupported as a matter of law or policy.

Judge Sarokin's failure to recognize that the "fears and anxieties" of patients mandated a finding that the tablet

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13. No one disputes that patients can be re-educated when provided with an explanation by physicians and pharmacists. But it is not the job of these health care professionals to create secondary meaning where none exists. According to the decisions below, Ciba's extensive sales and advertising had allegedly already delivered the proper message to consumers concerning the significance of appearance features. Obviously, if an explanation is still needed, the message was never received.

appearance was functional and had no secondary meaning was due to his well-intentioned, but misguided, belief that generic drugs should have a different appearance so that patients could exercise "informed consent" to any change in the source of their medicines. The concept of "informed consent" is clearly not part of any statutory or common law doctrine of unfair competition. Rather, it is an unwarranted attempt by the courts in the Third Circuit to legislate social policy and to interfere with the intended implementation of state substitution laws.

The courts below clearly disregarded the unique marketing environment of prescription pharmaceuticals and failed to differentiate this case from an everyday shopping situation in which the consumer's purchasing decision may be unfairly influenced by too close a similarity in appearance of adjacently displayed products. Here, as a Federal Trade Commission study has aptly noted, the physician prescribes, the pharmacist dispenses, and the patient pays.[14] As previously noted, no advertising or promotional activities are directed at patients, and prescription drugs are not purchased by choice or on impulse. The average patient neither knows nor cares if the name or appearance of a medication is associated with a single producer. The patients care only that they receive the medication which their doctor prescribed and that it works for the purpose intended. The state substitution laws are, in essence, nothing more than a recognition of these facts and the overriding fact that brand name prescription practices had totally deprived patients of any choice in the source of their medications, thereby causing unfairly high drug prices.

During the 1950's and 60's most states had in place "anti-substitution" laws which prohibited the pharmacist from dispensing any product other than the product specificially identified on the prescription.[15] These laws were originally intended

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14. Staff Report to the Federal Trade Commission, Drug Product Selection 96 (1979).

15. FTC Staff Report, *supra*, Note 14 at 146, *et seq.* The FTC Staff Report contains a thoroughly documented analysis of the role of the manufacturer, (Cont'd)

to prevent pharmacists from dispensing unsafe products, but they also provided significant economic impetus for major pharmaceutical companies to use promotional techniques designed to encourage brand name prescribing by physicians.

In 1962, Congress amended the Food, Drug and Cosmetic Act to include provisions requiring manufacturers of new drugs to establish, prior to marketing, that those drugs were safe and effective. *See* 21 U.S.C. §321, *et seq.* The FDA also established a code of good manufacturing practices to ensure that all products were not only identical in their composition and therapeutic value, but were also safely manufactured.

By the late 1960's, it had become apparent that the amendments to the Food and Drug law were working in a manner which assured that approved generic drugs were equivalent to their brand name counterparts, and this fact was publicly expressed by the regulatory experts at the FDA on numerous occasions.[16] This established equivalence of generic drugs to their brand name counterparts should logically have led to a rapid expansion in the rate of sale of those products in view of their significantly lower cost to consumers. Numerous reported studies over the past ten years have documented the significantly lower cost of generic drugs and the savings which are realized on generic drug purchases.[17]

(Cont'd)

physician, pharmacist, patient and State and Federal regulation in the distribution and selection of prescription drugs and the impact of these factors on competition.

16. *See,* for example, FDA Consumer Magazine, March 1973; FDA Consumer Magazine, February 1978.

17. FTC Staff Report, *supra,* Footnote 14 at 196-219; this Court has taken notice of studies establishing price differentials of up to 1200% for the same amount of a specific drug and concluded that "the phenomenon of widely varying drug prices is apparently national in scope." *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., supra,* at 754; Consumer Reports, January 1975, at page 48.

Despite the enormous price differentials, generic pharmaceutical products account for only a small share of the prescription pharmaceutical market. There can be no doubt that the use of the brand name as if it were the generic name and the state anti-substitution laws were responsible for that result. During the ten year period from 1968 to 1977, only 10% to 14% of all new prescriptions were written by physicians using the generic name of the medication, and that figure is inflated by a higher percentage of generic prescriptions for certain antibiotics.[18]

It was against this backdrop, that the states, acting to protect the health and welfare of their citizens, modified the anti-substitution laws and enacted laws which encouraged the substitution of lower-cost, therapeutically equivalent drugs for the brand name product actually set forth on a prescription.[19] It should be painfully obvious in view of the foregoing history that the assertion that the appearance of tablets and capsules is protectable trade dress, *i.e.*, functions as a trademark, amounts to nothing more than an attempt by Ciba and other brand name companies to erect a new barrier to the dispensing of lower-costing, generic equivalent drugs to replace the brand name barrier which was torn down by the state substitution laws. Such a barrier cannot be justified under the guise of "informed consent" even if, for the sake of argument, the concept of "informed consent" is valid. Product appearance differentiation is neither necessary nor desirable as a means of establishing such consent.

Although the mechanics of the state substitution laws vary from state to state, they are all based on a common principle, namely, that the use of a brand name on a prescription written by the doctor does not automatically mean that the brand name product will be dispensed. Depending upon the requirements of

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18. Annual Prescription Survey by The Albany College of Pharmacy, Medical Marketing and Media, April 1978 at 24; Multi-Source Drugs: An Acceleration in the Use of Lower-Costing Substitutes? Reynolds Securities Information Report, May 13, 1977.

19. *Pharmaceutical Society of NY Inc. v. Lefkowitz*, 454 F. Supp. 1175 (S.D.N.Y. 1978), *aff'd* 586 F.2d 953 (2d Cir. 1978).

a particular state, the physician must give some further indication that the use of the brand name was actually intended to command the pharmacist to dispense the brand name product and was not merely being used as a means of describing a type of medication. The New York substitution law[20], for example, requires the prescription form to recite that it will be filled generically unless the doctor signs over the line stating "dispense as written." The other signature line which must appear on the form reads "substitution permissible", and a signature on that line mandates the pharmacist to substitute a less expensive generic equivalent. Other state laws make substitution of a generic equivalent mandatory unless the physician vetoes such substitution by writing the words "dispense as written", "do not substitute", or similar terminology on the prescription form.[21]

The patient is not a stranger to the foregoing procedures since, in most instances, the patient see the prescription and carries it to the pharmacist. Moreover, the majority of prescriptions are written by the doctor in the presence of the patient at a time, and under circumstances where the patient's (and the doctor's) preference for a generic or brand name drug can be fully explored. There is no reason to believe that a patient is unaware that a generic drug may be dispensed rather than the brand name. Nor is there any reason to cause the patient any anxiety by changing the appearance of a medication.

Each of the state substitution laws also contains provisions for labeling the prescription container with information with respect to the name of the drug and the source of origin of the drug, and penalties to ensure compliance with these requirements. In New York and New Jersey, mislabeling is a crime and multiple

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20. N.Y. Education Law, Section 6810, 6815, 6816 (McKinney's Supp. 1981).

21. *See* Warner, Consumer Protection and Prescription Drugs: The Generic Substitution Laws, 67 Ky. L.J. 389 (1979) for an excellent discussion of the specific provisions of the State substitution laws and the differences between individual states.

violations of the labeling requirements can result in fines, imprisonment, and the loss of license to engage in dispensing prescription pharmaceuticals.[22] As noted in the decisions below and in the *Ives* case, these provisions are being enforced and indictments have been handed down. There is no reason to suppose that there will be widespread violation of these state laws by pharmacists. As this Court stated in *Virginia State Board of Pharmacy v. Virginia Citizens' Consumer Council, Inc.*, high professional standards, to a substantial extent, are guaranteed by the close regulation to which pharmacists are subject, and the pharmacists who are guilty of professional dereliction that actually endangers their customers will promptly lose their licenses. In any event, it is improper for a court to hold a generic drug manufacturer liable for unfair competition based upon product appearance simulation while simultaneously finding that patients associate that product appearance with the medication itself and not with its producer.

III.

The courts below disregarded the *Ives* decision and improperly applied Section 43(a) of the Lanham Act.

In *Ives*, this Court held that generic drug manufacturers are not liable for contributory infringement under Section 32 of the Lanham Act simply because they manufacture a "look-alike" drug and advertise that drug as a less expensive alternative to a brand name pharmaceutical product. It is now clear that "a finding of contributory infringement requires proof of either an intent to induce illegal substitution or continued sales to particular customers whom the manufacturer knows or should know are engaged in improper palming off."[23] The foregoing legal standard requires proof that the generic manufacturer intentionally induced the

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22. New York Education Law, Section 6816 (McKinney's 1981 Supp.).

23. This standard for determining contributory infringement is set forth in the concurring opinion of Justice White, 72 L. Ed. 2d at 618, *et seq.*, and is expressly adopted in the majority opinion, 72 L. Ed. 2d at 615, footnote 13.

pharmacists to mislabel generic drugs or, in fact, continued to supply generic drugs to pharmacists who were known to be engaged in mislabeling.[24]

This Court also stated that a rule which held generic manufacturers liable for acts of mislabeling committed by pharmacists merely because the generic manufacturers could "reasonably anticipate" illegal substitution or mislabeling would be a "watered down" and incorrect standard.[25] It adopted Justice White's concurring opinion which holds that the mere fact that some illegal substitution by some unknown pharmacists can be anticipated to some unspecified extent is insufficient to establish that a manufacturer is contributorily liable. As Justice White noted, there was no contributory infringement in *Snow Crest's* manufacture of a product identical in appearance to that of Coca-Cola in *Coca-Cola v. Snow Crest Beverages, Inc.*, 64 F. Supp. 980, 989 (D. Mass. 1946), *aff'd.*, 162 F.2d 280, *cert. denied*, 332 U.S. 809 (1947), although Judge Wyzanski recognized in *Snow Crest* that:

> "[A]ny man of common sense knows that in any line of business . . .there are some unscrupulous persons who, when it is to their financial advantage to do so, will palm off on customers a different product from that ordered by the customer." 64 F. Supp. at 988-989.

In the case below, the Third Circuit, relying on its earlier decision in *SK&F v. Premo* stated (625 F.2d at 1062):

> " . . .it has been held that it is actionable conduct under New Jersey law for a drug manufacturer to put a product in the hands of a pharmacist in a form in which the manufacturer can *reasonably anticipate* that it may be passed off as another

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24. 72 L. Ed. 2d at 615.

25. 72 L. Ed. 2d at 616, footnote 13. 27.

> product even if the manufacturer does nothing else to encourage passing off." [Emphasis added.)

That legal concept was overruled by *Ives*. Although *Ives* was decided under Section 32 of the Lanham Act, it clearly applies with equal force to the New Jersey common law rule since both are derived from the same precedent. Section 32 of the Lanham Act is a codification of the Supreme Court's decision in *Warner & Co. v. Eli Lilly & Co.*, and there is no suggestion that Congress intended to depart from that decision and other precedents in enacting Section 32 of the Lanham Act.[26] Moreover, the "reasonable anticipation" standard enunciated in *SK&F v. Premo* was expressly based on the Restatement of Torts, §§ 711 and 713, and the Restatement is expressly derived from *Warner*.

Any doubt concerning the question of whether the New Jersey rule is different is put to rest by the fact that the decision in *Warner* reversed a Third Court decision based on New Jersey common law. Moreover, unlike the facts here, that case included evidence of actual inducement of illegal substitution and not merely an allegation of "reasonable anticipation." *See Eli Lilly & Co. v. Wm. R. Warner & Co.*, 275 F. 752 (3rd Cir. 1921). In any event, the decisions of this Court in the *Sears* and *Compco* cases clearly preempt the application of state law in a manner which would enjoin the copying of appearance features. Those decisions clearly limit relief under state law to labeling or other notice provisions even in cases involving deliberate passing off.

The Third Circuit's attempt to evade the clear mandate of *Ives* with respect to Section 32 of the Lanham Act and the impact of *Sears* and *Compco* with respect to common law, by finding Bolar liable for "passing off" under Section 43(a) of the Lanham Act serves to demonstrate both the court's singlemindedness in searching for a theory to justify its decision and its lack of understanding of the law of unfair competition. In order to be guilty of a violation of Section 43(a), the party charged must be

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26. *See Ives* at 72 L. Ed. 2d at 620, footnote 2.

guilty of ". . .a false designation of origin or false description" with respect to goods or services which move in commerce. The undisputed facts of the present case establish that the only activity in which Bolar engaged was the manufacture and sale of a capsule which looked like the plaintiff's capsule. That activity cannot amount to a false description or designation of origin unless the appearance of the tablet has trademark significance, *i.e.*, designates a source of origin. Absent proof of secondary meaning, the facts of this case are indistinguishable from the facts considered by this Court more than sixty years ago in *Warner*. In that case, despite deliberate acts of passing off at the retail level, and actual inducement of those acts by the manufacturer, no relief was granted which would have required the manufacturer to change the appearance of the product because the appearance was functional and did not have source-indicating significance.

The generic substitution laws were enacted in recognition of the fact that the physician's use of the brand name as if it were the generic name and the anti-substitution laws were depriving the public of lower priced, but nevertheless, safe and effective, generic substitutes. In cases involving legal substitution—which is certainly the dominant use of generic drugs—no harm whatsoever is caused to the brand name manufacturer or the patient as a result of identical appearance. The patient gets precisely what the doctor ordered. The brand name company loses the sale only because the substitution laws provide the opportunity to buy a cheaper, equivalent product. Product appearance is irrelevant to the drug selection process.[27] In short, there is no passing off. Thus, forcing a color change serves no legitimate interest, but merely interferes with substitution by creating anxieties with respect to whether the right medication was dispensed.

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27. In *Pennwalt Corp. v. Zenith Laboratories, Inc.*, 472 F. Supp., 413, 422 (E.D. Mich. 1979), the court held drug look-alike case could not extend to dispensing doctors since they are not deceived. Precisely, the same logic applies to pharmacists and patients engaged in legal substitution.

CONCLUSION

The issues in this case affect the health and welfare of all citizens and deserve to be heard by this Court.

Respectfully submitted

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